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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,376	10/18/2001	Richard James Lewis	14455	8463

7590 12/31/2003  
Leopold Presser  
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EXAMINER

LIU, SAMUEL W

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 12/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/806,376

Applicant(s)

LEWIS ET AL.

Examiner

Samuel W Liu

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1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7, 13 and 19-20, drawn to an isolated  $\rho$ -conotoxin peptide and pharmaceutical composition comprising it, classified in class 514, subclass 2.
- II. Claim 8, drawn to a process of using the  $\rho$ -conotoxin peptide to test a molecule acting as an antagonist of  $\alpha 1$ -adrenoceptor activity, classified in class 430, subclasses 7.1.
- III. Claims 9-10 and 12, drawn to an isolated polynucleotide encoding a  $\rho$ -conotoxin peptide and a vector comprising the polynucleotide thereof, classified in class 536, subclass 23.1.
- IV. Claim 11, drawn to an antibody against the  $\rho$ -conotoxin peptide, classified in class 530, subclass 387.1.
- V. Claims 14-18 and 21-23, drawn to a method of treating a disease or disorder state comprising administering to a mammal the isolated  $\rho$ -conotoxin peptide, classified in class 514, subclass 2.

The inventions are distinct, each from the other for the following reasons:

Inventions I, III and IV are patentably distinct from one another because of the materially different structures of the compounds claimed. The Invention I is drawn to polypeptide and Invention III to polynucleotide while Invention IV is drawn to an antibody. The biopolymers that are the subject of each group are independent and/or patentable distinct from each other because each biopolymer is structurally distinct. The biopolymers of each invention would be expected to

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exhibit different physical and chemical properties, and are capable of separate manufacture or use.

In addition, Invention III is directed to polynucleotides that is classified in class 536, subclass 23.1, and/or to a cell into which polynucleotides is transferred and a vector where the polynucleotide is bale to directing biosynthesis of the gene product, which process would have been searched in class 435 subclass 69.1. Invention IV is directed to antibody that is classified in class 530, subclass 387.1. Thus, they acquire the different classification and are patentably distinct.

Invention III (polynucleotide) and Invention IV (antibody) are distinct from each other because of the materially different structures of the compounds claimed. The biopolymers that are the subject of each group are independent and/or patentable distinct from each other because each biopolymer is structurally distinct. The nucleic acid is composed of deoxyribonucleotides linked by phosphodiester bonds and forms a double helix as a stable conformation while antibody is composed of amino acid residues linked by peptide bonds. Thus, biopolymers of each invention would be expected to exhibit different physical and chemical properties, and are capable of separate manufacture or use.

Inventions I (polypeptide) and Invention IV (antibody) are distinct from each other because of the materially different structures of the compounds claimed. Although antibody is belong to a types of polypeptide, antibody is glycosylated and its tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associate via disulfide bonds into a Y-shaped symmetric dimer. Thus, the macromolecule of each invention would be expected to exhibit different physical and biochemical properties, and are capable of separate manufacture or use.

Invention I is related to Invention II as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product

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as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptide can be used to raise an antibody that binds the polypeptide thereof, for example.

Invention I is related to Invention V as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptide can be used in proteinchip array to investigate signal transduction pathway in which the polypeptide involves, for example.

Inventions III are unrelated to Inventions II and V. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, a polynucleotide is not the composition which involves a process of testing a molecule (Group II) or the composition which involves in a method of treating a disease state (Group V), and the polynucleotide can be used in mechanistically different/distinct process(s), e.g., plasma resonance surface plasma technology to investigate real time polynucleotide-protein interaction.

Inventions IV are unrelated to Inventions II and V. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, an antibody polynucleotide is not the composition which involves a process of testing a molecule (Group II) or the composition which involves in a method of treating a disease state (Group V), and the antibody can be used in mechanistically different/distinct process(s), e.g., immobilized on the gold surface of plasma resonance surface plasma to investigate real time protein-protein interaction.

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Inventions II and V are directed to different and/or distinct methods. Although there are no provisions under the section for "Relationship of Invention" in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper between the methods of Inventions II and V since they constitute patentably distinct inventions comprising distinct/different methodologies, starting material, objectives, technical considerations, ingredients, endpoint or/and treatment outcome. Therefore, each method is patentably distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art shown by their different classification, art recognized divergent subject matter, separate search, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the

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process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu, Ph.D. whose telephone number is 703-306-3483. The examiner can normally be reached Monday-Friday 9:00 -5:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communication and (703) 305-3014 for the after final communication. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.



Samuel W. Liu, Ph.D.

December 18, 2003



ROBERT A. WAX  
PRIMARY EXAMINER